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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,095	02/23/2004	Mark Peakman	4483-4	3528

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EXAMINER	
TSAY, MARSHA M	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,095	PEAKMAN, MARK	
	Examiner	Art Unit	
	Marsha M. Tsay	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Amendment received on April 27, 2005. Claims 1-17 are canceled. Claims 18-47 are pending and under examination.

The foreign priority document GB402129.1 was received June 2, 2005.

The instant application was filed February 23, 2004. This application claims foreign priority to GB402129.1 filed January 30, 2004. Therefore, the instant application received benefit to January 30, 2004.

Newly submitted claims 30-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to tolerance promoting cells.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-33, directed to cells, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawal of Objections and Rejections

The objection to the disclosure due to minor informalities is withdrawn.

The objection to the title as not being descriptive is withdrawn.

The objection to claim 14 due to minor informalities is withdrawn.

The objection to claims 7-12, 15 as being in improper form is withdrawn.

The rejection of claim 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement and written description requirement is withdrawn.

The rejection of claims 1, 3-5, 6, 9, 12-13, 15, 17 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

The rejection of claims 1-7 under 35 U.S.C. 101 as directed to non-statutory subject matter is withdrawn.

The rejection of claims 1, 8, 11-14 under 35 U.S.C. 102(b) as being anticipated by Chance et al. (WO 9634882) is withdrawn.

The rejection of claims 1, 6, 3-4 under 35 U.S.C. 102(b) as being anticipated by Filvaroff et al. (US20020058614A1) is withdrawn.

The rejection of claims 10, 16 under 35 U.S.C. 103(a) as being unpatentable over Meierhoff et al. (2002 Diabetes Metab. Res. Rev. 18: 367-380) in view of Peakman et al. (1999 J. Clin. Inves. 104(10): 1449-1457).

New Objections and Rejections

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-38 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 34-38 are drawn to peptides. Peptides are naturally occurring in cells and exist in nature. The claimed invention does not show

the "hand of man." Amending the claim to require that the peptide is purified or isolated would be remedial.

In the Response received April 27, 2005, Applicant asserts that the use of "consisting essentially of" terminology in the new claims will distinguish the claimed products from their prior existence as components of the naturally occurring intermediate polypeptide preproinsulin, and therefore render the 35 U.S.C. 101 rejections moot. However, this is not found persuasive because the terminology "consisting essentially of" is not closed claim language. Therefore, its interpretation as open claim language allows for anticipation by sequences having additional amino acid residues. In addition, as explained in the text of the 35 U.S.C. 101 rejection above, peptides exist in nature. As currently written, the instant claims are drawn to naturally-occurring products that do not indicate an intervention and/or improvement by man.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 24-25, 39-41 are drawn to peptides having the amino acid sequence depicted by the relevant SEQ ID NOs. The use of "having" a sequence renders the claim vague and unclear because "having" in common usage may include or contain other things.

Claims 30-33 are included in this rejection because they are dependent on claim 18.

Claims 19-23, 34-38 recite the language "consisting essentially of." It is unclear what "consisting essentially of" means in terms of polymers.

Claims 42, 44 are included in this rejection because they are dependent on claim 34.

Claims 24-25, 27-28, 30, 39-41, 46-47 recites the limitation "combination with one or more peptides or combination of peptides" in the claims. There is insufficient antecedent basis for this limitation in the claims or its dependent claim (18 or 19 or 34).

Claims 43, 45 are included in this rejection because they are dependent on claim 39.

Claim 26 recites combination of peptides. There is no basis for the combination of peptides in the claim because the claim does not teach or suggest how the peptides are to be combined. In addition, some of the modes of administration listed are repeated in the claim, for example, by "oral route" and "orally."

Claims 27-28, 39-40 recite "or more" in the claims. For example, claim 27 recites an amount of up to 1 mg or more per single dose. The claim is unclear as to how much more peptide is needed to make an effective dose because as written, the claim is drawn to an indefinite amount. The same line of reasoning applies to claim 28. For claims 39-40, the claims recite a combination of one or more peptides. Again, the claims are unclear as to how many additional peptides can be combined together.

Claim 29 is included in this rejection because it is dependent on claim 28.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Chance et al. (WO 9634882). Chance et al. teach polypeptide compounds wherein the peptide sequence comprises a human proinsulin bridging peptide (des(31-53)hPI) which is the sequence depicted as instant SEQ ID NO: 9 (p. 7, SEQ ID NO: 1, p. 11, SEQ ID NO: 3; claim 1). Chance et al. teach a method for treating diabetes mellitus and non-insulin dependent diabetes mellitus by administering to the organism an effective amount of a pharmaceutical formulation comprising the hybrid insulin/IGF-1 analog (p. 31; claim 1). Chance et al. teach that the compounds can be administered in a single daily dose or in multiple doses per day (p. 30, lines 28-30; claim 26). An effective amount and preferred dose that is administered is in the range of 10-100 ug/kg of active compound (p. 31, lines 13; claim 27). For an adult human, a typical daily dose is from 0.5 to 50 mg (p. 31, lines 14-15; claims 28-29).

In their response dated April 27, 2005, Applicants argue the Chance et al. reference is of little relevance to the instant invention. Applicants assert the type of therapy presented by Chance et al. is completely different from that of the instant invention. Additionally, Applicants assert although one of the bridging peptides used by Chance et al. has a sequence similar to that of the core sequence described in the present application, this bridging sequence is not intended to be prepared or used

otherwise than in covalent connection to the insulin A and B chains. Examiner acknowledges Applicants' arguments and will now address the assertions. Claim 1, as currently amended, is drawn to a method of treating a patient having Type 1 diabetes mellitus (T1DM) which comprises administering to the patient a patient having the sequence SEQ ID NO: 9. The use of claim language "having" in the instant case is interpreted as the same as the use of open claim language "comprising", which allows for anticipation by sequences having additional amino acid residues. Therefore, even if the sequence in des(31-53)hPI is a bridging sequence, the sequence still comprises or encompasses instant SEQ ID NO: 9 and meets the limitation of Claim 1. Claim 1 is silent as to the specific therapy that is utilized in the method of treating a patient having T1DM. As amended, the claim is still drawn to a method of treating a patient having T1DM which comprises administering to the patient a peptide having the sequence depicted as SEQ ID NO: 9. Therefore, claims 18, 26-29 are anticipated by Chance et al.

Claims 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Filvaroff et al. (US20020058614A1). Filvaroff et al. teach a SEQ ID NO: 13, where residues 13-32 correspond to instant SEQ ID NO: 4, residues 19-36 correspond to instant SEQ ID NO: 5, residues 22-38 correspond to instant SEQ ID NO: 6, and residues 13-38 correspond to instant SEQ ID NO: 10 (p. 70, SEQ ID NO: 13; claims 34-38).

In their response dated April 27, 2005, Applicants also argue the Filvaroff et al. reference is of no relevance. Applicants assert the Filvaroff et al. reference is concerned only with cartilagenous disorders and the peptide sequences included in the SEQ ID NOs referred to by the Examiner are parts of much larger sequences which have no application to T1DM therapy of any kind. Examiner acknowledges Applicants' arguments and will now address the assertions. Claims 34-38, as currently amended, are drawn to a peptide having a sequence consisting essentially of a sequence selected from the relevant SEQ ID NO. The use of "consisting essentially of" is interpreted as the same as open claim language "comprising" and therefore, allows for anticipation by sequences having additional amino acid residues.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-38, 42, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Filvaroff et al. (US20020058614A1). Filvaroff et al. teach a SEQ ID NO: 13, where residues 13-32 correspond to instant SEQ ID NO: 4, residues 19-36 correspond to instant SEQ ID NO: 5, residues 22-38 correspond to instant SEQ ID NO: 6, and residues 13-38 correspond to instant SEQ ID NO: 10 (p. 70, SEQ ID NO: 13). Filvaroff et al. disclose the insulin polypeptides and variants can be formulated into pharmaceutical compositions with acceptable carriers, excipients, and/or stabilizers (p.

46, [289]). Filvaroff et al. also disclose an article of manufacture containing materials useful for the diagnosis or treatment of various cartilagenous disorders, including diabetes mellitus (p. 52, [0038]).

It would have been obvious to a person having ordinary skill in the art to make a pharmaceutical composition comprising a peptide, such as instant SEQ ID NO: 10 or manufacture a kit comprising the peptide because Filvaroff et al. teach a polypeptide sequence comprising instant ID NO: 10 and suggest it in a form of a pharmaceutical composition and as a component of a kit.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 8, 2005

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER